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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,157	09/15/2003	Keith Charles Deen	GH-50017-2	4000

26130 7590 05/21/2004

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EXAMINER	
WEGERT, SANDRA L	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 05/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/663,157	DEEN ET AL.	
	Examiner	Art Unit	
	Sandra Wegert	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9 and 20, drawn to nucleic acids, recombinant methods of producing polypeptides and host cells comprising nucleic acids; classified in class 435, subclass 69.1+.

II. Claims 10 and 11, drawn to a TR7 polypeptide, classified in class 530, subclass 350+.

III. Claim 12, drawn to an antibody immunospecific for the TR7 polypeptide; classified in class 424, subclass 130.1+.

IV. Claim 13, drawn to a method of treating a subject by adding a TR7 agonist; classification dependent on structure of agonist.

V. Claim 13, drawn to a method of treating a subject using gene therapy; classified in class 536, subclass 23.5+.

VI. Claim 14, drawn to a method of treating a subject by adding a TR7 antagonist; classification dependent on structure of antagonist.

VII. Claim 14, drawn to a method of treating a subject by administering antisense; classified in class 536, subclass 23.5+.

VIII. Claim 15, drawn to a method of diagnosing a disease related to TR7 expression; classified in class 536, subclass 23.5+.

IX. Claims 16 and 18, drawn to a method of identifying ligands of TR7 using a competitive binding assay; classified in class 435, subclass 7.1+.

X. Claim 17, drawn to an agonist of TR7, classification dependent on structure of agonist.

XI. Claim 19, drawn to an antagonist of TR7, classification dependent on structure of antagonist.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for Inventive Groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons: Groups I-III, X and XI are independent and distinct, each from the other, because they comprise products which possess characteristic differences in structure and function, and each has an independent utility that is distinct for each invention which cannot be exchanged. The nucleic acids of group I can be used to make a hybridization probe or can be used in gene therapy as well as in the production of the protein of interest. The protein of Group II can be used to make an antibody or used therapeutically. The agonists and antagonists of Inventions X and XI can be used for in-situ identification of the TR7 polypeptide or can be used for treatment.

Groups I and II are also related as process of making and product made. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product, or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05 (f)). In the instant case the

polypeptide can be prepared by materially different processes, such as by chemical synthesis, or obtained from nature using various isolation and purification protocols.

Furthermore, Invention I is unrelated to Invention III. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotide is unrelated to the antibody because they are each used for different purposes and neither is produced by use of the other.

Invention I is unrelated to Invention IV, VI and IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotide is unrelated to methods that identify or administer a ligand of TR7.

Invention I is related to inventions V, VII and VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the polynucleotide of Invention I can be used to produce the TR7 polypeptide as well as for in-situ hybridization techniques in tissue and for administration of DNA for the treatment of disease.

Invention II is unrelated to Inventions IV-VIII, X and XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04,

MPEP § 808.01). In the instant case the polypeptide of Invention II is neither used in nor produced by any of the methods or products of Groups IV-VIII, X and XI, and is unrelated specifically to ligands of the TR7 polypeptide because of differing functions and effects.

Invention II is related to Invention IX as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the polypeptide of Invention II can be used to produce the antibody of Invention III, as well as to search for ligands.

Invention III is unrelated to Inventions IV-XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibody of Group III is neither used in nor produced by any of the methods or products of Groups IV-XI, and is unrelated specifically to ligands of the TR7 polypeptide because of differing functions and effects.

The methods of Inventions IV-IX are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals. Methods of treating a subject by adding ligands of TR7 are distinct from methods that administer DNA because they require different diseases, treatment protocol, and personnel, and have different chances of success. Methods of diagnosing a disease related to expression of TR7 are different from treatment methods in terms of materials,

personnel, goals and steps. In vitro binding assays using TR7 encompasses different subjects (cells versus multicellular organisms), probable different conditions, different protocols, and personnel, and have differing chances of success.

Invention IV is related to invention X as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the agonist of Invention X can be used for in situ localization of TR7 as well as to treat disease in a subject.

Invention IV is unrelated to Invention XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method Invention IV requires an agonist which would have a different structure from the product of Invention XI and would have different cellular and physiological effects.

Invention V is unrelated to Inventions X and XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method Invention V requires a polynucleotide, which has a different structure and function from a TR7 ligand.

Invention VI is unrelated to Invention X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or

they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of Invention VI requires a TR7 antagonist, which has a different structure and function than a TR7 agonist.

Invention VI is related to Invention XI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the antagonist of Invention XI can be used for in situ localization of TR7 as well as to treat a TR7-related disease in a subject.

Inventions VII and VIII are unrelated to Inventions X and XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Inventions VII and VIII require polynucleotides for their practice, rather than ligands of TR7.

Invention IX is related to Inventions X and XI as a process of detecting a compound and the product detected. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to find other and materially different product or (2) that the product as claimed can be detected by another and materially different process (MPEP § 806.05(f)). In the instant case the binding assay is a general assay not specific for the TR7 polypeptide and ligands for TR7 can be produced by testing structurally-related compounds.

Because these inventions are distinct for the reasons given above, as well as by their different classifications, divergent subject matter and different search requirements, restriction for examination purposes as indicated is proper.

In response to this requirement, applicants must elect from Groups I through XI. Applicant is advised that in order for the reply to this requirement to be complete it must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLW

17 May 2004

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER